K102163

OCT 16 2010

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
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Wendy Garman - Contact Person

Date Summary Prepared: July 2010

Device Name:

- Trade Name – RealSeal XT Sealer
- Common Name – Root Canal Sealant
- Classification Name – Root Canal Filling Resin, per 21 CFR § 872.3820

Devices for Which Substantial Equivalence is Claimed:

- Pentron Clinical, *SE Epiphany Root Canal Sealant*
- Dentsply, *AH Plus Root Canal Sealer*

Device Description:

RealSeal XT Sealer is intended for permanent obturation of root canals of teeth in combination with root canal points. The subject device is a self-etch methacrylate/epoxy resin root canal sealant in a catalyst/base paste formulation, which combines the methacrylate and epoxies resin chemistry. Due to its self-etching and adhering properties, *RealSeal XT Sealer* does not require the use of an etchant, primer or adhesive to achieve its intended function. It has also been designed for dual cure capabilities. That is, it not only self-cures after mixing the catalyst and base parts in a specific time period, but it can also be light cured by the doctor if there is a need to see an immediate hardening of the material, which facilitates the immediate cleaning of the material after a root canal filling procedure.
RealSeal XT Sealer will be packaged in a 4 ml dual-barrel syringe for both the catalyst and base parts. The material can be mixed using an auto-mixing tip attached to the syringe or the material can be mixed by hand on a paper pad, if desirable.

Intended Use of the Device:

RealSeal XT Sealer is indicated for permanent root canal obturation and sealing, in combination with root canal points or an obturator.

Substantial Equivalence:

RealSeal XT Sealer is substantially equivalent to two other legally marketed devices in the United States. *RealSeal XT Sealer* functions in a manner similar to and is intended for the same use as the SE Epiphany Root Canal Sealant (currently marketed by SybronEndo as RealSeal SE Root Canal Sealant) and as AH Plus Root Canal Sealer, marketed by Dentsply. With the exception of one component, the components used in the *RealSeal XT Sealer* are commonly used in a variety of other dental resin composite products. Further details regarding the subject component is provided in this submission.

RealSeal XT Sealer is a self-etch methacrylate/epoxy resin root canal sealant in a catalyst/base paste-paste formulation, which combines a modified methacrylate chemistry based upon SE Epiphany Root Canal Sealant and epoxies resin chemistry based upon AH Plus Root Canal Sealer . Due to its self-etching and adhering properties, *RealSeal XT Sealer* is similar to SE Epiphany Root Canal Sealant in that it does not require the use of an etchant, primer or adhesive to achieve its intended function. The bonding capabilities to both tooth structure and composite gutta percha point materials have improved in *RealSeal XT Sealer*; however, the application procedures and indications have not changed.

Biocompatibility studies have been completed, which demonstrates that *RealSeal XT Sealer* is safe for its intended use.

This 510(k) submission also includes data from bench testing used to evaluate the performance characteristics of *RealSeal XT Sealer* compared to the predicate devices. The characteristics evaluated include working time, water solubility and bond strength.

Based upon the biocompatibility tests and bench testing, the clinical performance of *RealSeal XT Sealer* is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

OCT 16 2010

Re: K102163
Trade/Device Name: RealSeal XT Sealer
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Codes: KIF
Dated: July 26, 2010
Received: August 2, 2010

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

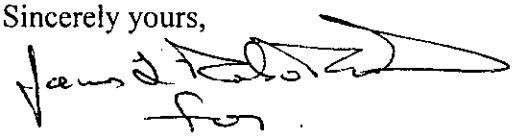
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

OCT 1 6 2010

510(k) Number (if known): K102163

Device Name: *RealSeal XT Sealer*

Indications For Use:

RealSeal XT Sealer is indicated for permanent root canal obturation and sealing, in combination with root canal points or an obturator.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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